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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/743,625

12/22/2003

Arthur M. Krieg

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7590 11/20/2009
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EXAMINER

MINNIFIELD, NITA M

ART UNIT

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1645

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/743,625	Applicant(s) KRIEG ET AL.	
	Examiner N. M. Minnifield	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' amendment filed August 14, 2009 is acknowledged and has been entered. Claims 1-18 have been canceled. Claim 19 has been amended. Claims 19-39 are now pending in the present application. All rejections have been withdrawn in view of Applicants' comments with the exception of those discussed below.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 19-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 42-47, 49-53, 56, 57, 82-

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85, 90, 92, 94, 96, 98, 100, 102 and 103 of copending Application No. 09/337584. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite claims directed to a method for treating asthma in a subject, comprising administering to the subject an effective amount for treating asthma in the subject of an immunostimulatory oligonucleotide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 19-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 23, 31, 32 and 34-37 of copending Application No. 10/769282, now allowed. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite claims directed to a method comprising administering to the subject an immunostimulatory oligonucleotide. Although 10/769282 does not recite treatment for asthma, this would be the result since the methods steps are the same. Application 10/769282 recites a method of modulating an immune response, the administration of the immunostimulatory oligonucleotide modulates a Th1 immune response, which is the immune response modulated in an asthmatic subject that has received the immunostimulatory oligonucleotide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 19-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-29 and 31-33 of copending Application No. 10/894862. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite claims directed to a method comprising administering to the subject an immunostimulatory oligonucleotide. Although 10/894862 does not recite treatment for asthma, this would be the result since the methods steps are the same. Application 10/894862 recites a method of inducing a Th1 immune response and suppressing a Th2 immune response, the administration of the immunostimulatory oligonucleotide modulates a Th1 immune response, which is the immune response modulated in

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an asthmatic subject that has received the immunostimulatory oligonucleotide; the Th2 immune response is suppressed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. The provisional obviousness-type double patenting rejections over 09/337584, 10/769282 and 10/894862 are maintained. Applicants' arguments filed August 14, 2009 have been fully considered but they are not persuasive. Applicants have asserted that the rejections are provisional since none of the claims in the 09/337584, 10/769282 and 10/894862 applications have been found allowable. If any of the cited claims are found allowable, Applicants will address the rejection.

With regard to 09/337584, Applicants have indicated that they will consider filing a terminal disclaimer if the claims are allowed after the Interference. No decision has been rendered.

With regard to 10/769282 it is noted that this application was allowed September 4, 2009. A terminal disclaimer or amendment to the claims is required.

With regard to 0/894862, it is requested that the rejection be held until allowable subject matter in any of the cited applications is identified. The provisional rejection will be maintained until a properly filed terminal disclaimer is received.

7. Claims 19-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 11-38, 40 and 42-49 of U.S. Patent No. 7605138. Although the conflicting claims are not identical, they are not patentably distinct from each other both application and issued patent recite claims directed to a method comprising administering to the subject an immunostimulatory oligonucleotide. Although 7605138 does not recite treatment for asthma this would be the result since the methods steps are the same.

8. Claims 19-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9-26, 48 and 49 of U.S. Patent No. 7576066. Although the conflicting claims are not identical, they are not patentably distinct from each other

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both application and issued patent recite claims directed to a method comprising administering to the subject an immunostimulatory oligonucleotide. Although 7576066 does not recite treatment for asthma this would be the result since the methods steps are the same.

9. Claims 19-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9-23, 43, 44 and 46-48 of U.S. Patent No. 7569553. Although the conflicting claims are not identical, they are not patentably distinct from each other both application and issued patent recite claims directed to a method comprising administering to the subject an immunostimulatory oligonucleotide. Although 7569553 does not recite treatment for asthma this would be the result since the methods steps are the same.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 19-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of "without an allergen in an amount effective to treat asthma". Line 2 recites only an immunostimulatory oligonucleotide being administered. Does the "amount effective" refer to the allergen or the immunostimulatory oligonucleotide? Does Applicant intend "wherein the immunostimulatory oligonucleotide is administered, *without an allergen*, in an amount effective to treat asthma"?

12. No claims are allowed.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. M. Minnifield/
Primary Examiner, Art Unit 1645
November 18, 2009